



# Department of Justice

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## **JUSTICE DEPARTMENT WILL NOT OPPOSE CEO ROUNDTABLE ON CANCER'S PROPOSAL**

WASHINGTON — The Department of Justice announced today that it will not oppose a proposal by the CEO Roundtable on Cancer (CRC) to develop and publicize model contract language for clinical trials of potential new cancer treatments. The Department said the language is not likely to be anticompetitive and can be used to help increase efficiency in contract negotiations, potentially reducing costs and shortening the time needed to begin clinical trials.

The Department's position was stated in a business review letter from Thomas O. Barnett, Assistant Attorney General for the Antitrust Division, to counsel for the CRC.

The CRC and the National Cancer Institute (NCI) will jointly lead the project to develop model language for clinical trials. The CRC is a non-profit organization whose goal is to make continuous progress toward the elimination of cancer as a personal disease and public-health problem. The NCI is the federal government's principal agency for cancer research and training and is part of the U.S. National Institutes of Health.

The CRC requested a business review letter from the Division expressing its enforcement intentions regarding the CRC's and NCI's proposal to develop and publicize model clauses for use in clinical-trial agreements. Clinical-trial agreements typically involve three parties: a pharmaceutical or medical-device company known as a "sponsor"; a hospital, clinic, or university where the research is performed, known as the "research institution"; and the physician who is in charge of the trial, known as the "principal investigator."

"Making the model language available to sponsors, research institutions, and principal investigators, as proposed by CRC, is not likely to reduce competition," Barnett said in the letter. In the letter, Barnett explained that the "model language does not contain any provisions specifying prices or rates," and that "[w]hether to use the language or any of its provisions will be left to the determination of each party acting independently."

Under the Department's business review procedure, an organization may submit a proposed action to the Antitrust Division and receive a statement as to whether the Division currently intends to challenge the action under the antitrust laws.

A file containing the business review request and the Department's response may be examined in the Antitrust Documents Group of the Antitrust Division, U.S. Department of

Justice, 450 Fifth Street, NW, Suite 1010, Washington, D.C. 20530. After a 30-day waiting period, the documents supporting the business review will be added to the file, unless a basis for their exclusion for reasons of confidentiality has been established under the Business Review Procedure.

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